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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,150	08/30/2006	Jean-Francois Butty	MEMI-2	6130

7590 02/03/2009

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EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,150	BUTTY ET AL.	
	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *23 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and arguments, received on October 10th, 2008, have been fully considered by the examiner. Claims 13-24 are currently pending with claims 18 and 19 amended. Applicant's amendment to the specification obviates the objection to the drawings and applicant's amendment to claims 18 and 19 obviates the rejection under 35 U.S.C 112 second paragraph. Applicant's arguments, see page 1, page 5 - page 6, line 15, filed October 20th, 2008, with respect to the rejection(s) of claim(s) s 13-24 under 35 USC 103 have been fully considered and are persuasive. The rejection under 35 U.S.C 103 of July 21st, 2008 has been withdrawn. The following response forms the new grounds of rejection of the currently pending claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claim 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22, the recitation therein is unclear and confusing rendering the scope of the claim unascertainable. With specific regard to the recitation of "supplying electrical power ... puncture performed by the catheter", it is unclear if the seal described is formed such that it is formed between the catheter and the punctured tissue or if the tissue is sealed to itself thereby completely sealing the puncture site.

4. Claims 23 and 24 are rejected for their dependency on the above rejected claim 22.

Claim Rejections - 35 USC § 103

5. Claims 13-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Tu et al (US Pat. No. 5,938,659) and Eggers et al (US Pat. No. 6,312,428).

Regarding claim 13, Champeau discloses a catheter (catheter **10**) containing at least one pair of electrodes capable of functioning in a bipolar manner and at least two end electrodes arranged towards opposed ends of the catheter on either side of the pair of aforementioned electrodes capable of functioning in a monopolar manner (electrodes **30**, **32**, **34**, **36**, **38**). Champeau further discloses a plurality of supply channels (apertures **68**) capable of perfusing saline solution around the electrodes (see col. 8, lns. 4-9). Champeau fails to specifically recite the limitation of a pointed tip for piercing insertion and for the plurality of supply channels+ to be contained with the area defined by the bipolar electrodes. Tu discloses a similar catheter containing a plurality of electrodes and further discloses the electrodes to contain supply channels for the perfusion of saline solution around the electrodes (hollow passage **20**, see col. 7; 17-27). Tu fails to discloses the inclusion of a sharp tip on the catheter. Eggers discloses a similar device to that of Champeau and Tu containing a plurality of electrodes functioning in an electrosurgical manner. Eggers further discloses the inclusion of a sharp tip on a catheter to facilitate the placement of the device in a target portion of tissue (see figures 2A, 3 and 7; col. 7; 18-24). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Champeau with a sharp tip and a plurality of supply channels containing within the bipolar electrodes. The inclusion of a sharp tip is something old and well known in the art which allows for easier insertion of the catheter into the target tissue.

Furthermore, as evidenced by Eggers, such a sharp distal tip is utilized with structures containing a plurality of distal electrodes. Additionally, the provision of the supply channels being contained in the bipolar electrodes, as evidenced by Tu provides for the perfusion of a fluid directly to the area around the electrodes ensuring that a treatment fluid is present in the area surrounding the electrode. Lastly, both the provisions of Tu and Eggers can be provided on the device of Champeau by common fabrication methods known to one of ordinary skill in the art.

Examiner notes that Applicant has claimed statements of intended use and other functional limitations, for example "adapted to function in bipolar mode" and "adapted to function in monopolar mode". Such limitations fail to structurally distinguish the claims from the prior art of record, which is capable of being used as desired. Since the prior art structure is capable of performing the intended use, then it meets the claim. In each instance that a statement of intended use is relied upon, the same standard as mentioned above will be applied.

Regarding claim 14, Champeau fails to disclose the bipolar electrodes at least two saline solution supply channels (lumen **66**). Tu in view of the above rejected claim 13 provides for at least two supply channels per electrode (see figures 3 and 5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for a similar number of supply channels in each electrode as that of Tu on the device of Champeau in order to facilitate the perfusion of a liquid to the area surrounding each electrode.

Regarding claim 15, Champeau discloses liquid supply channels (lumen **66**) with outlets (bores **68**) arranged near the front and rear ends of the catheter and for the supply of a treatment liquid to be capable of being supplied to any of the outlets independent of the other outlets (see col. 8, lns. 4-12).

Regarding claim 16, Champeau discloses a plurality of electrodes (electrodes **30**, **32**, **34**, **36**, **38**) disposed on the catheter body with electrode (electrode **34**) arranged between two other electrodes (see figure 1). Champeau further discloses for the electrode to be capable of supplying monopolar energy (see col. 3, lns. 30-34).

Regarding claim 18, in view of the above rejected claims 13 and 16, it would have been obvious to one of ordinary skill in the art at the time the invention was made that with the supply channels placed in view of Tu on the bipolar electrodes would possess a an arbitrary distance from the monopolar electrode which is sufficient to avoid being in a region of coagulated tissue formed around the monopolar electrodes.

Regarding claim 19, Champeau discloses a catheter (catheter **10**) containing at least one pair of electrodes capable of functioning in a bipolar manner and at least two end electrodes arranged towards opposed ends of the catheter on either side of the pair of aforementioned electrodes capable of functioning in a monopolar manner (electrodes **30**, **32**, **34**, **36**, **38**). Champeau further discloses a plurality of supply channels (apertures **68**) capable of perfusing in an individually controllable manner, saline solution around the electrodes (see col. 8, lns. 4-12). Champeau fails to specifically recite the limitation of a pointed tip for piercing insertion, for the plurality of supply channel to be contained with the area defined by the bipolar electrodes or for the inclusion of two pumps to supply the saline to the bipolar electrodes. Tu discloses a similar catheter containing a plurality of electrodes and further discloses the electrodes to contain supply channels for the perfusion of saline solution around the electrodes (hollow passage **20**, see col. 7; 17-27). Tu fails to disclose the inclusion of a sharp tip on the catheter. Eggers discloses a similar device to that of Champeau and Tu containing a plurality of electrodes functioning in an

electrosurgical manner. Eggers further discloses the inclusion of a sharp tip on a catheter to facilitate the placement of the device in a target portion of tissue (see figures 2A, 3 and 7; col. 7; 18-24). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Champeau with a sharp tip and a plurality of supply channels containing within the bipolar electrodes. The disclosure by Champeau of the individual control of the supply of liquid would require multiple pumping/supply means to allow for selective delivery of saline solution as well as individual control of injection rate. The inclusion of a sharp tip is something old and well known in the art which allows for easier insertion of the catheter into the target tissue. Furthermore, as evidenced by Eggers, such a sharp distal tip is utilized with structures containing a plurality of distal electrodes. Additionally, the provision of the supply channels being contained in the bipolar electrodes, as evidenced by Tu provides for the perfusion of a fluid directly to the area around the electrodes ensuring that a treatment fluid is present in the area surrounding the electrode. Lastly, both the provisions of Tu and Eggers can be provided on the device of Champeau by common fabrication methods known to one of ordinary skill in the art.

Regarding claim 20, Champeau discloses a temperature acquisition unit (microprocessor-based control system, see col. 8, lns. 24 – 30) connected to the thermocouples within the catheter.

Regarding claim 21, Champeau discloses an RF generator associated with the apparatus. Champeau further discloses a computing unit (microprocessor-based control system; see col. 7; 66 - col. 8; 29) connectable to the temperature acquisition unit, pumps and RF generator functioning to provide control and monitoring of the operations (see col. 8, lns. 24-30).

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Tu et al (US Pat. No. 5,938,659) and Eggers et al (US Pat. No. 6,312,428) and further in view of Houser et al (US Pub. No. 2002/0035361 A1).

Regarding claim 17, in view of the above rejected claim 13 Champeau discloses thermocouples disposed within the catheter tip and functioning to measure the temperature of the surrounding tissue. Tu additionally discloses the inclusion of a temperature sensor associated with the distal end of the disclosed device to assess the temperature of the tissue. Champeau, Tu and Eggers fails to disclose the thermocouples to be retractably mounted in the catheter. Houser et al discloses a catheter containing a plurality of central bores (**146**) and side bores (**148**) with temperature sensors (**150**) retractably disposed within the bores (see paragraph [0086]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the retractable temperature sensors disclosed by Houser et al with the above described device of rejected claim 13 to allow for a catheter with sensing means insertable into the surrounding tissue. Each invention is directed towards the same inventive concept radiofrequency ablation to tissue with temperature monitoring and the disclosed structure of Champeau in view of Tu and Eggers readily allows for such temperature sensors of Houser et al to be disposed within the catheter. The combination would further provide for a device which can sense temperature at increased depth sin the surrounding tissue thereby allow for greater control and assessment of the treatment progress.

Allowable Subject Matter

5. Claim 22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

6. Claims 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: While Champeau in view of the disclosure of Mulier et al (US Pat. No. 6,537,248 B2) represents the closet prior art of record, neither discloses or provides for a combination which provides for each of the limitations presented in claim 22. Additionally, in view of applicant's remarks filed October 20th, 2008, none of the prior art of record sets forth a method of radiofrequency ablation wherein the electrical power is first supplied to the monopolar electrodes to seal the puncture caused by the catheter such that the tissue forms a seal with the catheter. The prior art of record additionally fails to provide for the perfusing of saline into the now sealed portion of tissue and the subsequent supply of bipolar RF energy in order to effectuate thermal ablation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

RJH